

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Maheswaran et al.

Appl. No.: 10/646,784

Filed: August 25, 2003

For: Use of Mullerian Inhibiting Substance and Interferon for

Treating Tumors

Confirmation No. 1100

Art Unit: 1614

Examiner: To Be Assigned

Atty. Docket: 0609.5130001/LBB/FRC

Information Disclosure Statement under 37 C.F.R. § 1.97(b)

Commissioner for Patents PO Box 1450 Alexandria, VA 22313-1450

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97, and 1.98. Copies of documents AA1-AK1, AA2-AK2, AA3-AK3, and AA4-AB4 are not provided in accordance with the U.S. Patent and Trademark Office pre-OG notice of July 11, 2003, which states "the Office hereby waives the requirement under 37 CFR 1.98 (a)(2)(i) for submitting a copy of each cited U.S. patent and each U.S. patent application publication for all U.S. national patent applications filed after June 30, 2003." Copies of all other cited documents are provided.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

This Information Disclosure Statement is being filed before the mailing of a first Office Action on the merits. No statement or fee is required.

It is respectfully requested that the Examiner initial and return a copy of the enclosed PTO 1449, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Frank R. Cottingham Attorney for Applicants

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Date: June 16, 2004

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	AA1	4,40	4,188	09/13/1983	Donahoe et al.	07/2	9/1981			
	AB1	4,48	37,833	12/11/1984	Donahoe et al.	03/0	1/1982			
	AC1	4,75	3,794	06/28/1988	Donahoe	06/2	1/1986			
	AD1	4,89	7,355	01/30/1990	Eppstein et al.	10/2	9/1987			
	AE1	4,94	6,787	08/07/1990	Eppstein et al.	10/2	7/1989	•		
	AF1	5,01	.0,055	04/23/1991	Donahoe		Filed: 04/25 a) Date: 04/2			
	AG1	5,01	.1,687	04/30/1991	Donahoe et al.	10/2	9/1985			
	AH1	5,04	7,336	09/10/1991	Cate et al.	10/3	0/1985			
	AI1	5,04	9,386	09/17/1991	Eppstein et al.	05/1	5/1990			
	AJ1	5,11	0,904	05/05/1992	Haviv et al.	07/1	0/1990	······································		
	AK1	5,13	39,941	08/18/1992	Muzyczka et al.	10/2	07/10/1990 10/25/1991			
				FOREIGN P.	ATENT DOCUMENTS					
EXAMINER INITIAL		DOCU	MENT NUMBER	DATE	COUNTRY	CLAS	S SUB-CLASS	TRANSLATION		
	AL1	WO 8	39/06695 A1 ,	07/27/1989	WIPO			Yes No		
-	AM1	WO 9	00/11092 A1 /	10/04/1990	WIPO			Yes No		
	AN1	WO 9	94/12650 A1	06/09/1994	WIPO			Yes No		
	A01	WO 9	94/29469 A1 !	12/22/1994	WIPO			Yes No		
	AP1	WO 9	95/16709 A2	06/22/1995	WIPO			Yes No		
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	AR	1	Recombinant P	Human Interfe cly in Health	rative Pharmacokine eron Beta-la (IFNβ- ny Male and Female	-la) Product	s Administer	ed		
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	AT	1	Attisano, L. BioMed Centra		flich, S.T., "The Sast 2001)	Smads," <i>Gen</i> d	ome Biol. 2:3	010.1-3010.87		
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			TO-1449		APPLICANT Maheswaran et al.				
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INITIAL		DOCU	MENT NUMBER	DATE	NAME	FILI	NG DATE		
	AA2	5,17	3,414	12/22/1992	Lebkowski et al.	10/3	0/1990		
	AB2	5,19	8,420	03/30/1993	Donahoe et al.	06/3	0/1992	<u> </u>	
	AC2	5,31	0,880	05/10/1994	Donahoe et al.	04/1	2/1991		
	AD2	5,35	4,678	10/11/1994	Lebkowski et al.	12/2	1/1992		
	AE2	5,35	9,033	10/25/1994	Cate et al.		Filed: 06/23 e) Date: 07/2		
	AF2	5,42	7,780	06/27/1995	Cate et al.	10/0	5/1992		
	AG2	5,43	6,146	07/25/1995	Shenk et al.	01/2	1/1993		
	AH2	5,45	9,127	10/17/1995	Felgner et al.	09/1	6/1993		
	AI2	5,47	4,935	12/12/1995	Chatterjee et al.	07/2	5/1994		
	АЈ2	5,47	8,745	12/26/1995	Samulski et al.	12/0	4/1992		
,	AK2	5,48	4,768	01/16/1996	Donahoe et al.		U.S Filed: 03/08/199 102(e) Date: 03/08/1		
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	AL2	WO 9	6/29411 A1 /	09/26/1996	WIPO			No	
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	AS	2			rle, P.A., "Apoptosis Biology (1997)	s: Activa	e NF-кВ or d	ie?" <i>Curr</i> .	
	AT	<u>2</u>	in Boys thro	ughout Pubert	J.M., "Serum Levels of y and in the First 7 5-247, The Endocrine	Two Years	of Life," J .		
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	AA3	5,53	8,892	07/23/1996	Donahoe et al.	11/04/	1993			
	AB3	5,54	7,854	08/20/1996	Donahoe et al.	10/04/	1994			
	AC3	5,58	9,377	12/31/1996	Lebkowski et al.	06/06/	1995			
	AD3	5,58	0,859	12/03/1996	Felgner et al.	03/18/	1994			
	AE3	5,58	9,466	12/31/1996	Felgner et al.	01/26/	1995			
	AF3	5,66	1,126	08/26/1997	Donahoe et al.	07/07/	1994			
	AG3	5,59	3,972	01/14/1997	Weiner et al.	09/21/	1993			
	АНЗ	5,65	2,224	07/29/1997	Wilson et al.	02/24/	1995			
	AI3	5,67	6,954	10/14/1997	Brigham	05/08/	1995			
	АЈЗ	5,69	3,622	12/02/1997	Wolff et al.	06/07/	1995	CLASS TRANSLATION Yes NO Yes NO Yes		
	AK3	5,70	3,055	12/30/1997	Felgner et al.	01/26/	1994			
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	AR	3 <u> </u>	Surgery, and	Technology,	napter 25. Androgens," Adashi, E.Y., et al., PA, pp. 505-525 (1995	eds, Li				
	AS	<u>3</u>	Barkett, M. and Gilmore, T.D., "Control of apoptosis by Rel/NF-xB transcription factors," Oncogene 18:6910-6924, Stockton Press (1999)							
	АТ	<u>3</u>	Baron, S., et al., "The Interferons. Mechanisms of Action and Clinical Applications," J. Am. Med. Assoc. 266:1375-1383, American Medical Association (1991)							
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	AR	4	Baron, S. and	d Dianzani, I	F., "The interferons: a viral infections," Ant.	biologi	cal system v			
	Barrie, S.E., et al., "Biochemistry and Pharmacokinetics of Potent Non-steroidal Cytochrome P450 _{17α} Inhibitors," J. Steroid Biochem. Molec. Biol. 60:347-351, Elsevier Science Ltd. (1997)									
	AT	<u>4</u>	Behringer, R.R., et al., "Abnormal sexual development in transgenic mice chronically expressing Müllerian inhibiting substance," Nature 345:167-170, Macmillan Publishers (1990) /							
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	АТ	<u>6</u>	Cate, R.L., et al., "Isolation of the Bovine and Human Genes for Müllerian Inhibiting Substance and Expression of the Human Gene in Animal Cells," Cell 45:685-698, Cell Press (1986) /					
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	AR	7	cancer Drug,	et al., "Deve " <i>Cold Sprin</i> g atory (1986)	elopment of Mulleri g Harbor Symposia Q	an Inhibit: uant.Biol.	ng Substance LI:641-647,	as an Anti- Cold Spring	
	AS	2	Cate, R.L., et al., "Mullerian Inhibiting Substance: A Fetal Growth Inhibitor with Homology to TGF-β," J. Cell. Biochem. Supplement 12A:183, Abstract No. D005, Alan R. Liss (1988)						
	AT	7	Chapman, R.S., et al., "A novel role for IRF-1 as a suppressor of apoptosis," Oncogene 19:6386-6391, Nature Publishing Group (2000)						
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	AS	Chin, T., et al., "Human Müllerian Inhibiting Substance Inhibits Tumor Growth in Vitro and in Vivo," Cancer Res. 51:2101-2106, American Association for Cancer Research (1991)							
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	AS	Clumeck, N. and Hermans, P., "Antiviral Drugs Other than Zidovudine and Immunomodulating Therapies in Human Immunodeficiency Virus Infection," Am. J. Med. 85:165-172, Excerpta Medica (1988)								
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	AR	<u>11</u>	Cells for Tre	eatment of Ex	Vivo Gene Transfer wit perimental Brain Tumors the Advancement of Scie	," Scie	ence 256:1550		
	AS	Culver, K., et al., "Lymphocytes as cellular vehicles for gene therapy in mouse and man," Proc. Natl. Acad. Sci. USA 88:3155-3159, National Academy of Sciences (1991)							
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	di Clemente, N., et al., "Cloning, Expression, and Alternative Splicing of the Receptor for Anti-Müllerian Hormone," Mol. Encrinol. 8:1006-1020, The Endocrine Society (1994)									
	AT	<u>12</u>	Doherty, G.M., et al., "Interferon Regulatory Factor Expression in Human Breast Cancer," Ann. Surg. 233:623-629, Lippincott, Williams & Wilkins, Inc. (May 2001)							
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	AT	<u>15</u>	Engelhardt, J.F., et al., "Adenovirus-Mediated Transfer of the CFTR Gene to Lung of Nonhuman Primates: Biological Efficacy Study," Human Gene Ther. 4:759-769, Mary Ann Liebert, Inc. Publishers (1993)						
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	AS 16 Evan, G.I., et al., "Induction of Apoptosis in Fibroblasts by c-myc Protein," Cell 69:119-128, Cell Press (1992)								
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	Ferrantini, M., et al., "IFN-αl Gene Expression into a Metastatic Murine Adenocarcinoma (TS/A) Results in CD8* T Cell-Mediated Tumor Rejection and Development of Antitumor Immunity. Comparative Studies with IFN-γ-Producing TS/A Cells," J. Immunol. 153:4604-4615, The American Association of Immunologists (1994)								
	АТ	<u>17</u>	Ferrantini, M., et al., "α ₁ -Interferon Gene Transfer into Metastatic Friend Leukemia Cells Abrogated Tumorigenicity in Immunocompetent Mice: Antitumor Therapy by Means of Interferon-producing Cells," Cancer Res. 53:1107-1112, American Association for Cancer Research (1993)						
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	AS	<u>18</u>	Fraley, R., et al., "Entrapment of a bacterial plasmid in phospholipid vesicles: Potential for gene transfer," Proc. Natl. Acad. Sci. USA 76:3348-3352, National Academy of Sciences (1979)					
	AT	<u>18</u>	Fraley, R., et al., "Introduction of Liposome-encapsulated SV40 DNA into Cells," J. Biol. Chem. 255:10431-10435, American Association for Biochemistry and Molecular Biology (1980) —					
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	AS	Fynn-Thompson, E., "Müllerian Inhibiting Substance Regulates Steroidogenesis in Rodent Leydig Tumor Cell Lines," Slides Presented at Harvard Medical School Prematriculation Summer Program Presentation, 13 pages (1998)							
	AT	<u>19</u>	developing ma FASEB J. 14:1	Geymayer, S. and Doppler, W., "Activation of NF- κ B p50/p65 is regulated in the developing mammary gland and inhibits STAT5-mediated β -casein gene expression," FASEB J. 14:1159-1170, The Federation of American Societies for Experimental Biology (2000) \checkmark					
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	AT	21	Hudson, P.L., et al., "An Immunoassay to Detect Human Mullerian Inhibiting Substance in Males and Females during Normal Development," J. Clin. Endocrinol. Metabol. 70:16-22, Williams and Wilkins (1990)						
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	AS	22	Huang, J., et al., "Essential role of bilary glycoprotein (CD66a) in morphogenesis of the human mammary epithelial cell line MCF10F," J. Cell Sci. 112:4193-4205, The Company of Biologists Ltd. (1999)						
	AT	22	Malignant Br	Huang, J., et al., "Expression of Biliary Glycoprotein (CD66a) in Normal and Malignant Breast Epithelial Cells," <i>Anticancer Res. 18</i> :3203-3212, J.G. Delinassios (1998)					
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	Josso, N., et al., "Anti-Müllerian Hormone: The Jost Factor," in: Recent AS 23 Progress in Hormone Research, Bardin, C.W., ed., Academic Press, Inc., San Diego, CA, pp. 1-59 (1988)								
	AT	23	Josso, N., et al., "Anti-Müllerian hormone in early human development," Early Human Develop. 33:91-99, Elsevier Scientific Publishers Ireland Ltd. (1993)						
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	AS	<u>24</u>	Kaido, T., et al., "IFN-α ₁ Gene Transfection Completely Abolishes the Tumorigenicity of Murine Bl6 Melanoma Cells in Allogeneic DBA/2 Mice Decreases Their Tumorigenicity in Syngeneic C57BL/6 Mice," <i>Int. J. Cancer</i> 60:221-229, Wiley-Liss, Inc. (1995)					
	АТ	24	Kanamaru, C., et al., "Smad7 Is Induced by Norepinephrine and Protects Rat Hepatocytes from Activin A-induced Growth Inhibition," J. Biol. Chem. 276:45636-45641, The American Society for Biochemistry and Molecular Biology, Inc. (December 2001)					
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	AS	<u>25</u>	Kasid, A., et al., "Human gene transfer: Characterization of human tumor-infiltrating lymphocytes as vehicles for retroviral-mediated transfer in man," Proc. Natl. Acad. Sci. USA 87:473-477, National Academy of Sciences (1990)							
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	AS	26	the tumor su	Kirchhoff, S. and Hauser, H., "Cooperative activity between HER oncogenes and the tumor suppressor IRF-1 results in apoptosis," <i>Oncogene 18</i> :3725-3736, Nature Publishing Group (1999)							
	АТ	<u>26</u>	Kleinerman, D.I., et al., "Consistent Expression of an Epithelial Cell Adhesion Molecule (C-CAM) during Human Prostate Development and Loss of Expression in Prostate Cancer: Implication as a Tumor Suppressor," Cancer Res. 55:1215-1220, American Association for Cancer Research (1995)								
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	AT	27	Kowalik, T.F., et al., "E2F1 Overexpression in Quiescent Fibroblasts Leads to Induction of Cellular DNA Synthesis and Apoptosis," J. Virol. 69:2491-2500, American Society for Microbiology (1995)								
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	AS	<u>28</u>		Kretzschmar, M. and Massague, J., "SMADs: mediators and regulators of TGF-β signaling," Curr. Opin. Genet. Develop. 8:103-111, Current Biology (1998)							
	AT	28	Kurian, M.S., et al., "Cleavage of Müllerian Inhibiting Substance Activates Antiproliferative Effects in Vivo," Clin. Cancer Res. 1:343-349, American Association for Cancer Research (1995)								
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	АТ	<u>29</u>	Lee, M.M., et al., "Mullerian Inhibiting Substance un Humans: Normal Levels from Infacny to Adulthood," <i>J. Clin. Endocrinol. Metab.</i> 81:571-576, The Endocrine Society (1996)							
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	AS	<u>30</u>		Lengyel, P., "Biochemistry of Interferons and Their Actions," <i>Ann. Rev. Biochem.</i> 51:251-282, Annual Reviews Inc. (1982)							
	AT	<u>30</u>	Luo, W., et al., "Suppression of tumorigenicity of breast cancer cells by an epithelial cell adhesion molecule (C-CAM1): the adhesion and growth suppression are mediated by different domains," Oncogene 14:1697-1704, Nature Publishing Group (1997)								
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	AS	<u>31</u>	Deregulation	Lyet, L., et al., "Ontogeny of Reproductive Abnormalities Induced by Deregulation of Anti-Müllerian Hormone Expression in Transgenic Mice," <i>Biol. Reprod.</i> 52:444-454, Society for the Study of Reproduction (1995)							
	АТ	<u>31</u>		MacLaughlin, D.T., et al., "Bioassay, Purification, Cloning, and Expression of Müllerian Inhibiting Substance," <i>Meth. Enzymol.198</i> :358-369, Academic Press Inc. (1991)							
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	AS	32	Malone, R.W., et al., "Cationic liposome-mediated RNA transfection," <i>Proc. Natl. Acad. Sci. USA 86</i> :6077-6081, National Academy of Sciences (1989)							
	AT	<u>32</u>	Miller, A.D., "Retrovirus Packaging Cells," Human Gene Ther. 1:5-14, Mary Ann Leibert, Inc., Publishers (1990)							
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	AS	<u>33</u>	Cell Growth	Miyazaki, M., et al., "Transforming Growth Factor-β1 Stimulates or Inhibits Cell Growth via Down- or Up-Regulation of p21/Waf1," Biochem. Biophys. Res. Commun. 246:873-880, Academic Press (1998)								
	AT	33	Moolten, F.L. and Wells, J.M., "Curability of Tumors Bearing Herpes Thymidine Kinase Genes Transferred by Retroviral Vectors," <i>J. Natl. Cancer Inst. 82</i> :297-300, Oxford University Press (1990)									
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	AS	34	for Mammalia	Muzyczka, N., "Use of Adeno-Associated Virus as a General Transduction Vector for Mammalian Cells," <i>Curr. Topics Microbiol. Immunol. 158</i> :97-129, Springer- Verlag (1992)							
	AT	34	Breast Cance	Nakshatri, H., et al., "Constitutive Activation of NF-kB during Progression of Breast Cancer to Hormone-Independent Growth," <i>Molec. Cell. Biol.</i> 17:3629-3639, American Society for Microbiology (1997)							
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	AS	<u>35</u>	Prostate Mici	rosomes and i	nibition of Androgen Syn n Male Rats by Novel St ine Society (1999)			
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	AS	38	alone and in	combination n nude mice,"	riproliferative effects of with natural interferon of Breast Cancer Res. Trea	gamma	on human bre	east
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	AT	42	responsible	for its effec	eptors for anti cts on steroido 594-599, Nation	genesis a	nd cell	differentia	ation," Proc.
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Rosenberg, M.B., et al., "Grafting Genetically Modified Cells to the Dama AT 44 Brain: Restorative Effects of NGF Expression," Science 242:1575-1578, Ame Association for the Advancement of Science (1988)	ged rican
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	AR	<u>51</u>		and Future F	noglutethimide and Ketoc Prospects," J. Steroid B				
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	AR	<u>52</u>	Immortalized	Human Breast	plation and Characteriza Epithelial Cell Line, I on for Cancer Research (MCF-10	" Cancer Re		
	Sovak, M.A., et al., "Aberrant Nuclear Factor-xB/Rel Expression and the Pathogenesis of Breast Cancer," J. Clin. Invest. 100:2952-2960, The American Society for Clinical Investigation, Inc. (1997)								
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	AS	Takahashi, M., et al., "Müllerian inhibiting substance as oocyte meiosis inhibitor," Molec. Cell. Endocrinol. 47:225-234, Elsevier Scientific Publishers Ireland, Ltd. (1986)							
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